On the even greater need for precaution under global change

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Summary

The greater the potential for disastrous, large-scale, or catastrophic impacts on health, the greater the case for precaution. The imperative for precautionary action, critical also for downstream determinants of health, is at least as compelling where macro-level concerns about the sustainability of life on Earth are at issue. In this context, I propose that a higher threshold of uncertainty is needed where large-scale harms to health and well-being are possible. Initial efforts must focus on the training of researchers and risk managers for competencies in complexity, and in systems approaches to transdisciplinary enquiry. Revisiting the intent behind Bradford Hill on causation is an essential first step. Focus on the more proximate causes of diseases, such as those related either to occupational exposures or to more downstream environmental exposures, is left to others in this collection.

***Key words*: catastrophic events, ecosystem health, epidemiology, ethics, evidence, prevention, sustainability, values**

Uncertainty, values, preventive medicine and precaution

Uncertainty is inherent to science[1]. In testing hypotheses, statistical significance and power are pre-specified or calculable entities that have associated with each of them a probability that decisions reached cannot be supported by the data; hence, the inherent nature of uncertainty in science[1]. This, together with issues of complex systems, leads to the apparent paradox that science is rarely 100% certain about anything that it investigates[1-5].

Uncertainties become more frequent - and larger - as we move from more proximate relationships between cause and effect under the reductionist scientific paradigm, to more distant and complex relationships between cause and effect under the systems approach to scientific enquiry. In the latter context, interactions among determinants in a causal pathway become all the more prominent. Indeed, the larger the system, the more important are the relationships likely to be among the greater number of determinants in the causal pathway. In summary, the more upstream or distant the determinants are from the effect, the more complex will be the relationships, with greater associated uncertainties[1, 6, 7].

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Risk assessors and risk managers can use the uncertainties that emerge from scientific enquiry, in both the reductionist and systems approaches, in different ways depending on implicit and/or explicit values that underlie their decisions. The risk assessor's use of uncertainty is toward inferring causation, while in risk management, uncertainty is used as a function of whose interests are being defended or promoted. Indeed, it has been shown that different scientists investigating the same data about causation can apply the same criteria in ways that produce opposite conclusions concerning cause and effect[8]. It is to implicit value differences, perhaps related to the training of the scientists involved, that discrepant conclusions are attributed[8].

Epidemiology is the science that is basic to informing public health policy. Its focus is on primary prevention[1]. Its role is to identify sources of exposure amenable to intervention. Exposures refer to all sources of potential impact on the health of people, including voluntary and involuntary exposures related to behavioural and environmental influences on health.

By stopping or minimizing exposure at the source, one is practicing preventive medicine. By extension then, the notion of prudence or precaution in the face of risk is thus commonplace in the public health sciences. The old maxim "an ounce of prevention is worth a pound of cure" applies[1, 5].

Since 1997, two major United States of America-based conferences have taken place on the topic of "The Precautionary Principle", and each produced consensus statements intended to influence how science is used in policy. First, the Wingspread 1998 Statement on The Precautionary Principle asserts: "When an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically"[2, 9].

The Lowell Summit in 2001, asked: "How does environmental science need to be developed to more effectively support preventive, precautionary decisions under conditions of uncertainty and complexity?" It proposed changes in the practice of science to better protect public health and the environment. The environment is recognized as essential to providing nature's services that support all life, including that of humans. A shift to more precautionary policies creates opportunities and challenges for scientists to think differently about the conduct of studies and the communication of results[3, 4, 10]. The Summit discussions centred on conceptualising these changes, especially when complex and uncertain threats must be addressed.

The decision to take risks is ultimately a deeply personal one, rooted in individual values and beliefs that collectively reflect cultural norms. It is proposed that what justifies precautionary action will vary as a function of individual, community and national values reflected respectively in our local, regional and national institutions.

Context

Concern for the negative impact of the human enterprise on the sustainability of ecosystems essential to human health and well-being has been well-documented[6, 7]. This paper focuses on the consequences of global changes for public health, and therefore it is more concerned with environmental and ecosystem impacts, as opposed to occupational impacts, on population health. The ethics of the latter impacts fall more into the category of micro-level ethics (i.e., the physician-patient relationship) or meso-level ethics (i.e., the community health officer-community relationship) impacts on health.

Global change, on the other hand, falls under macro-level ethics, concerned with the ethics of large-scale, population-wide, environmental and ecosystem impacts on human health**.** The distinction between macro- and micro-level ethics is made, not to subordinate micro-and meso-level ethical concerns, but more to bring attention to macro-level ethical concerns at a conference in which no other paper does so.

Respective analogues lie in the relationship between global health professionals and the global community, and the relationship between the physician and his/her patient. In the latter case, the physician advocates for the patient; in the former case, the global health professional advocates for population health on a global scale. Not that one is more deserving of attention than the other, but rather that macro-level concerns have not been given as much attention as what micro-level ethical concerns have; hence, the focus of this paper.

In relation to prevention, I argue that the greater and more wide-spread a potential impact, or the greater its population attributable risk, the greater the attention that should be given to precautionary action. Because the consequences for human health and well-being from global change are orders of magnitude more impacting than those from occupational health hazards, it is suggested that precautionary actions are even more critical for minimizing harm, because such large numbers of people could be negatively affected. This is not to understate the importance of avoiding even a single case of preventable morbidity or mortality, but rather to emphasize that the impacts from collapsing life-support systems will be several orders of magnitude greater.

Global change and public health

Over the past few decades, ecologists and biologists have been cautioning about environmental systems degrading at rates and on a scale hitherto unprecedented and with expanding reach[6, 7, 11, 12]. Depletion of the ozone layer, climate change, over-population, consumptiveness and waste, and the inappropriate uses of technology provide some examples. The link between the degradation of nature's services[13] and human health and well-being had been ignored until recently. Epidemiologists need to treat such evidence at least in the same way as what they would treat anecdotal evidence, and work with it in their role as advocates for public health[11, 14, 15].

I suggest that environmental epidemiologists and public health researchers have neglected the integration of ecological and biological evidence into their research agendas. Therefore, addressing complexity and systems approaches has been the domain of few [7, 12]. Grave risks exist for the health and well-being of humanity world-wide from global changes already underway[6, 11, 12, 15-18]. Global changes with negative implications for health are driven by population growth, over-consumption, and the inappropriate uses of technology[19]. These changes already have negatively impacted biodiversity and the climate system, with implications for ecosystems upon which humans depend for their health and well-being. Continuing to focus our training on reductionist approaches to the exclusion of systems approaches will not equip our students both with the tools and the wisdom needed to address the challenges posed by global change. Noting that life-supporting ecosystems continue to be eroded, systems approaches become all the more urgent for studies of either the current or of the future even more potentially serious global change impacts on public health.

The need for precaution becomes all the more evident in the global change context because of its scale and reach. The long-term nature of its effects, the complexity of the systems affected, the interactions among the various upstream determinants impacting on downstream eco- and biological systems, and the likely irreversibility of the trends once they have been set in motion (e.g., climate change) all underscore the need for precaution, because it may be too late to modify determinants by the time that harms have begun to be realized. In this context, resources channelled into prevention would be but a fraction of those potentially required for coping with and responding to catastrophic events on a global scale.

Because the risk assessor's mission must also be to estimate the risks from global change so as to better inform risk managers about these potential impacts, we need to explore how inadequately we equip our students for this role. Recognition of the need to help redirect science becomes apparent when we examine what it is that we teach about global change and public health. Because this topic requires competence in both complexity as well as transdisciplinary approaches in research[20], bold new initiatives are needed to equip researchers with these skills[21, 22]. In fact, what are our students currently learning about transdisciplinary research? What are we teaching them about causal inference? One example of each follows:

Transdisciplinary research

The thrust of most science training programmes is in reductionist science, seeking a single cause for an identified effect[23]. While this paradigm has unquestionably advanced knowledge, its real effect on the improvement of the lot of humanity is questionable[24-26]. The fault likely lies in the fact that reductionist approaches are incapable of taking multiple factors into account when examining economic, social and health interactions. Indeed, more and more it is being recognized that the complex nature of systems requires a transdisciplinary approach to addressing issues beyond those determinable through reductionism.

One step advanced from pure reductionism would be the bringing together of more than just a single discipline to address a particular issue. According to the Webster's Dictionary[27], *multidisciplinary* is defined as "Many… , multiple … , more than two … disciplines". Yet, we need not only to speak <u>at</u> one another, we need to speak <u>with</u> one another. This leads to the notion of "interdisciplinary research". *Interdisciplinary* is defined as "Involving two or more academic, scientific, or artistic disciplines".

But, in fact, arising from engagements among two or more disciplines emerges *transdisciplinary*, which Webster's defines as "Interdisciplinary". The Oxford Dictionary[28] defines *transdisciplinary* as "Of or pertaining to more than one discipline or branch of learning; interdisciplinary". In some dictionaries the word simply does not exist[29]. In fact, transdisciplinary approaches to human health could be defined something like: "Approaches that integrate the natural, social and health sciences in a humanities context, and in so doing transcend each of their traditional boundaries. Emergent concepts and methods are the hallmark of the transdisciplinary effort"[12, 15].

Clearly, the classical dictionary definitions are not enabling of shifts in scientific approach. Thus, what we are teaching is hardly conducive to competence in the current age of global change where particular concern about the interactive effects within complex systems needs to be addressed.

Causal inference

The Bradford Hill "criteria"[1] for causal inference are often applied in assessing whether an observed epidemiological association is causal in nature. The criteria that are applied to the findings of a single study of association between a putative exposure and a health outcome are:

- strength of evidence,
- consistency across studies,
- specificity of effects,
- temporality of effects,
- biological gradient (dose-response),
- plausibility of effects,
- coherence with other knowledge,
- experimental evidence,
- analogy based on experience.

But, despite these criteria, or so-called "aspects", Bradford Hill cautions for a "broad interpretation of the evidence". He notes the need to use the criteria as a guide to help answer if there is any other way to explain the set of facts before us. He urges us not to discount associations because there is insufficient evidence or understanding at one point in time. Most importantly, he emphasizes that causal judgements do not require perfect information and must be considered in the context of available knowledge and a responsibility to protect health[30].

Bradford Hill further cautions: "What I do not believe … is that we can usefully lay down some hard-and-fast rules of evidence that must be obeyed before we accept cause and effect". Hill concludes: "All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time"[31].

Yet, what we teach our students rarely includes the latter cautions noted by Bradford Hill. Instead, we provide students with a set of criteria for application at will, in as routine a fashion as desired. This does not provide for a role of "wisdom" in assessing the significance of a finding. In particular, where the upstream environmental determinants of health are concerned, the distant nature of the exposure is always likely to generate greater uncertainty compared to, say, that of a more proximate determinant. This leaves our trainees as technicians with poor aptitude for assessing causality and, in particular, for the need to apply precaution in the face of uncertainty.

A role for epidemiology

Ecologists have postulated that "global ecological integrity" is a function of "population", "affluence (or consumption)", and "technology". The three interact in ways that will determine sustainability[11, 12, 14, 15, 19]. Precaution thus becomes all the more prominent in the assessment of the above interacting determinants because the consequences of wrong decisions could be damaging to the public health on a grand scale. Working with complexity, through systems approaches, is needed because it can take into account these three large areas of enquiry under the functional relationship that defines the connection been global health and its upstream determinants. Epidemiology has the potential, if it embraces these concerns, to play a full role in this much-needed domain of transdisciplinary research[14].

Transdisciplinary research cannot be undertaken without due regard to the principles of bioethics, adding to the transdisciplinary mix of the research approach, if risk managers are to be informed by epidemiology. The four main principles of bioethics are[32]:

- beneficence (do good),
- non-maleficence (do no harm),
- respect for autonomy (respect for persons; respect the individual's right to self-determination),
- social and distributive justice (equity; those taking risks should also derive benefits).

Sub-principles, like those of veracity and fidelity (under "respect for autonomy") derive from these main principles[32] and have been incorporated into the ethics guidelines for environmental epidemiologists[33]. These also are of relevance to global change, including the duty to:

- protect the most vulnerable in society,
- involve communities in our research,
- protect the interests of future generations,
- serve the public health interest above any other interest.

Environmental epidemiologists must seize the challenge presented here by studying the more upstream determinants of public health, because no other discipline has the potential to inform the process as what epidemiology does[14]. Indeed, Soskolne and Broemling proposed that a sub-specialty under that of environmental epidemiology, namely "eco-epidemiology", be charged with this mission. Its primary goal must be to promote transdisciplinary approaches to serve the public health interest in the long-term. Along the way, new metrics will be needed that demonstrate the utility of the approach. Above all, appealing to the wisdom of Bradford Hill[31] and integrating this into our present-day teaching will go a long way toward our contributing to a sustainable future.

Eco-epidemiology presents the greatest opportunity for re-evaluating scientific tools to better address complexity and uncertainty with respect to ecosystem influences on public health. Epidemiologists, more than other scientists, are trained to prevent adverse health outcomes by making effective linkages between research on hazardous exposures and diseases. Moving into transdisciplinary approaches expands what they are already doing. Epidemiologists assess cumulative and interactive effects, identify vulnerable sub-populations, and develop systems approaches to their investigation. They are expert in surveillance and the identification of early warnings, and they command comprehensive techniques for analysing and communicating risks associated with hazards and uncertainty. The challenge before us then is to translate the recommended changes into concrete methods, proposals, and recommendations to best suit the domain of eco-epidemiology.

Research needs

The needs of research pertain first to graduate training and to building capacity. Curricula must include an understanding of what constitutes the study of complexity and systems approaches in transdisciplinary research. Evidence from scenario-based risk assessment has an additional layer of uncertainty that adds to the policy-makers' conundrum. Thus, the role of epidemiologists could be of optimal social benefit if they were to work with sociologists and pollsters in linking global change to human health for elucidating social values surrounding the health consequences of global change. Such information from the work of transdisciplinary teams could inform policy about the weight to be assigned to considerations of risk in the presence of uncertainty for resolving value conflicts and ethical tensions.

Main points for teaching about precaution

The Precautionary Principle is a “compass” to guide and improve decision making under uncertainty and complexity[5, 9]. There is no formula for determining when there is enough evidence for cautionary action. When to act should be assessed on a case-by-case basis, considering all of the evidence. It should be a function of both the strength of the evidence on risk, and the ability to prevent harm. Risk management decisions are ultimately politically determined[9, 23].

We cannot reduce precaution to a single decision-rule. Flexibility is needed to consider the nature of the risk, limitations in the science, populations exposed, accumulated knowledge and scientific “suspicion”[10]. We need to consider the cumulative strength of scientific evidence. Flexible rules and protocols are needed for the application of the Precautionary Principle. But, we also must consider the magnitude of potential impacts, availability of alternatives, and level of uncertainty. Politics always come into play, and hence the need exists for a participatory process that includes political science so that community values can be incorporated throughout any scientific enquiry[10, 23, 33].

Protecting the public interest above any other interest

Above all else in environmental epidemiology research, we must ask: “Who is deriving the benefits while who is taking the risks?”[23, 33] This question is directly relevant because the dominant culture’s values will permeate every step of the enquiry. Indeed, those wielding power will protect the interests of their own constituency over those interests of marginalized communities[23]. Thus, the proposed field of eco-epidemiology will find its role extending to bridge resulting inequities from research undertaken to support vested interests that are designed to support the dominant culture.

Eco-epidemiologists must be equipped with critical abilities to route out scientific research that is not impartial, whether of a reductionist or a complex systems nature[33]. They must be able to demonstrate when research is undertaken to serve special interests that are not consistent with the values of both individual worth and sustainable development[33, 34].

Any research that potentially will embarrass the establishment, or that might suggest changes to business as usual approaches, is likely to be subjected to various kinds of pressures[35]. For instance, researchers could find themselves being discouraged from pursuing such lines of enquiry, or they will be influenced to modify their research methods so that causal judgements are more difficult to reach. On completion of their research, they could find themselves being pressured not to publish their findings[35]. Indeed, vested interests can also employ scientists to undertake studies to create uncertainties that delay preventive actions, as in the tobacco story[36, 37]. Vigilance on the part of the research scientist is always necessary. In fact, the case has been made for institutional safeguards to protect scientists who are obstructed from performing their work in the public interest[38]. Tactics that obstruct and delay policy that could protect the environment and, in turn, the public health must be able to be exposed by eco-epidemiologists. In so doing, eco-epidemiologists will be honouring the principle of precaution in protecting the public health.

There is a tendency to under-regulate under conditions of scientific uncertainty and complexity, in preference to maintaining the *status quo*. While false-negatives have high costs to public health and the economy, false-positives are often quickly caught. A recent contribution to understanding the human cost of these types of delays has been published by the

European Environmental Agency[39]; it provides an analysis of a dozen case studies of the costs from acting later than one could or ought to have acted.

Because we have only one Earth, matters pertaining to negative impacts from global change become all the more important. In particular, great caution is needed on matters pertaining to the essence of life (namely, to its biological ingredients), as well as to the environments that sustain life (namely, to the determinants of ecosystem services). Evidence, however infirm or uncertain, that human activity is having adverse effects on either biological or ecosystem functioning, demands the highest level of concern with full implementation of the Precautionary Principle - if only because of its consequences for human health and well-being.

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